

**Advisory Action  
Before the Filing of an Appeal Brief**

<b>Application No.</b> 10/537,280	<b>Applicant(s)</b> SANDERS ET AL.
<b>Examiner</b> Cherie M. Woodward	<b>Art Unit</b> 1647

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 14 September 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.  
 b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.  
 Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
 (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
 (b) ☐ They raise the issue of new matter (see NOTE below);  
 (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.  
 NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. ☒ Applicant's reply has overcome the following rejection(s): 35 USC 101 over claims 200-203.

6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: 200 and 201.

Claim(s) objected to: 134, 135 and 203.

Claim(s) rejected: 121, 122, 126, 127, 129, 130, 133, 136, 137, 198 and 202.

Claim(s) withdrawn from consideration: 157-159, 162-171, 173-179 and 182-195.

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: \_\_\_\_\_

12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_

13. ☒ Other: See Continuation Sheet.

/Cherie M. Woodward/  
Primary Examiner, Art Unit 1647

Continuation of 13. Other: Applicant's arguments and amendments filed 9/14/2009 have been fully considered. The amendments to claims 200 and 202 are sufficient to overcome the rejection of record under 35 USC 101. Applicant's arguments regarding the rejection under 35 USC 102(b) over the '137 publication are not persuasive. As stated of record, it is a basic tenet of the antibody arts that polyclonal serum is comprised of a multiplicity of monoclonal antibodies - each antibody being produced by a unique Bcell and each Bcell producing a unique monoclonal antibody. All one need to do is to isolate any particular monoclonal antibody of interest from polyclonal serum. Applicant's claims recite the open-language transitional phrase "comprising." The composition may contain other material, including other monoclonal antibodies, as is the case with polyclonal serum. Applicant's arguments have been addressed of record. See, for example, the Office Action mailed 6/2/2009. This same principle of polyclonal serum comprising monoclonal antibodies is carried over in the rejection under 35 USC 103(a) and the rejection is maintained for these same reasons. The claims use the open-language "comprising" and accordingly, the composition may contain other material, including other monoclonal antibodies. Applicant's arguments have been addressed in the Office Action mailed 6/2/2009. Additionally, Applicant's arguments directed to the references individually, are not appropriate when the rejection is based on the combination of the references. Regarding the rejection of claim 202 under 35 USC 102(b), the amendment that the binding partner bind the TSH receptor is noted. However, the structure of the binding partner of claim 202 is only defined by one CDR selected from a Markush Group. It is well-established in the antibody arts that antibodies consist of 6 CDRs, each of which contribute to binding specificity to varying degrees. However, the two CDR3s typically contribute the most to binding specificity. Because claim 202 does not recite which VH CDR the recited sequences represent and because the Office does not have the facilities to test whether the antibodies disclosed by the prior art would bind TSH receptor (from any species) as well as, TNF, for example, the burden is on Applicant to show a novel and unobvious difference between the binding partners of claim 202 and those of the prior art. Claim 203 is objected to as being dependent on a rejected claim, but would otherwise be allowable if rewritten to include all of the limitations of the independent claim. The provisional ODP rejection of record over copending application 12/333714 is maintained for the reasons of record. The examiner apologizes for the typographical errors in the serial number in the Office Action of 6/2/2009 regarding the ODP rejection. Applicant is also correct in that a word processing error inadvertently occurred on p. 11 of the 6/2/2009 Office Action. The claims filed on 9/14/2009 are entered.